CONCLUSION

For the reasons set forth above and in defendants' Consolidated Memorandum, the claims against AstraZeneca should be dismissed.

Dated: Boston, Massachusetts
September 15, 2003

Respectfully submitted,

By: Lucy Fowler

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CERTIFICATE OF SERVICE

I certify that on September 15, 2003, a true and correct copy of the foregoing Memorandum in Support of AstraZeneca Pharmaceuticals LP's Motion to Dismiss the Amended Complaint was served on all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to Verilaw Technologies for posting and notification to all parties.

Lucy Fowler

Lucy Fowler

#4

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456
THIS DOCUMENT RELATES TO: *County of Suffolk v. Abbott Labs, Inc., et al* 03-CV-10643-PBS	CIVIL ACTION: NO. 01-CV-12257-PBS Judge Patti B. Saris

MEMORANDUM IN SUPPORT OF AVENTIS PHARMACEUTICALS INC.'S MOTION TO DISMISS THE COUNTY OF SUFFOLK'S AMENDED COMPLAINT

Defendant Aventis Pharmaceuticals Inc. ("Aventis Pharmaceuticals") respectfully submits this memorandum in support of its Motion to Dismiss the County of Suffolk's Amended Complaint ("CSAC"). In addition to the reasons set forth in the Consolidated Memorandum of Law in Support of Defendants' Motion to Dismiss the Complaint, the CSAC should be dismissed as to Aventis Pharmaceuticals because the County of Suffolk **fails to allege it has paid for any drug product Aventis Pharmaceuticals manufactured or sold.**[1] Accordingly, Plaintiff has failed to state a claim against Aventis upon which relief can be granted and its claims must be dismissed with prejudice.

On January 13, 2003, this Court advised the class action plaintiffs that in order to survive a motion to dismiss they must "particularize exactly what drugs, exactly what the fraud

[1] Aventis Pharmaceuticals Inc. hereby adopts and incorporates herein each of the arguments set forth in the Consolidated Memorandum of Law in Support of Defendants' Motion to Dismiss the Complaint.

is,[and] which plaintiffs paid for what drugs." See Tr. Of Jan. 13, 2003 Hearing on Motion to Dismiss, at 74. In May, 2003, the Court reaffirmed its statements, granted, in part, defendants' motions to dismiss and instructed the plaintiffs that if they amend their complaint they must "clearly and concisely allege with respect to each defendant: (1) the specific drug or drugs that were purchased from defendant; (2) the allegedly fraudulent AWP for each drug; and (3) the name of the specific plaintiff(s) that purchased the drug." *In re Pharm. Industry Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003).

The County of Suffolk filed its initial Complaint in this matter on January 14, 2003. On July 31, 2003, as a result of this Court's rulings on the motions to dismiss, the County of Suffolk filed its Amended Complaint with this Court. In order to meet the first two prongs of the Court's three part test, the County of Suffolk parroted the Amended Master Consolidated Complaint by identifying the specific drug products it paid for and listing AWPs for those products on attached Exhibits A and B to its Amended Complaint. (*See* Amended Complaint ¶ 4 and Exhibits A and B). The County asserts that the defendants' alleged inflation of AWPs for the Medicaid Covered Drugs set forth in the attached Exhibit A resulted in millions of dollars of overcharges to the County. Amended Complaint ¶ 4.

In Paragraph 161 of the Amended Complaint, the County references Anzemet® and Taxotere®, two drug products manufactured by Aventis Pharmaceuticals. The County fails, however, in the remaining four hundred-eighteen paragraphs of the Amended Complaint, to allege that it paid for either Aventis Pharmaceuticals product. Nor does the County include either product or any other product manufactured by Aventis Pharmaceuticals in the list of Medicaid Covered Drugs which it claims it paid for and which are the subject of the Amended Complaint (*See* Amended Complaint ¶ 4 and Exhibits A and B). Inasmuch as the County does

not claim it paid for any product manufactured by Aventis Pharmaceuticals and specifically omits any Aventis Pharmaceuticals product from the list of Covered Drugs on which the County bases its injuries, the County has failed to state a claim against Aventis Pharmaceuticals upon which relief can be granted. Accordingly, Aventis Pharmaceuticals Inc. respectfully requests that the County of Suffolk's claims be dismissed with prejudice.

Dated: September 15, 2003

Respectfully submitted,

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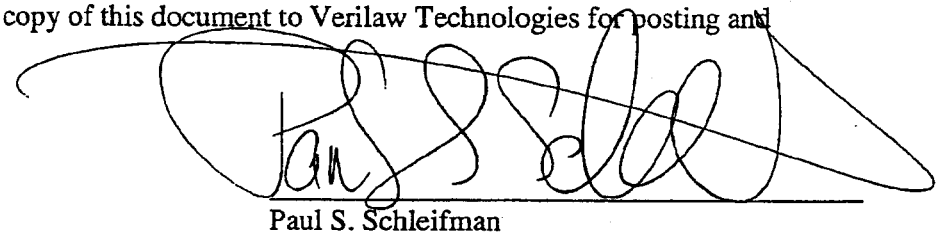
ATTORNEYS FOR AVENTIS PHARMACEUTICALS INC.

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the foregoing was served, this 15th day of September, 2003, to all counsel of record by electronic service pursuant to Case Management Order No. 2, by sending a copy of this document to Verilaw Technologies for posting and notification to all parties.



Paul S. Schleifman

#5

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION *THIS DOCUMENT RELATES TO:*	MDL NO. 1456
COUNTY OF SUFFOLK, Plaintiff, v. ABBOTT LABORATORIES, INC., AGOURON PHARMACEUTICALS, INC., AMGEN, INC., ASTRAZENECA PHARMACEUTICALS L.P., ASTRAZENECA US, AVENTIS BEHRING, AVENTIS PHARMACEUTICALS, INC., BARR LABORATORIES, INC., BAYER AG, BERLEX LABORATORIES, INC., BIOGEN, INC., BRISTOL MYERS SQUIBB COMPANY, ELI LILLY AND COMPANY, FUJISAWA PHARMACEUTICAL COMPANY, LTD., GENENTECH, INC., GLAXO WELLCOME, P.L.C., GLAXOSMITHKLINE, PLC, IMMUNEX CORPORATION, IVAX CORPORATION, IVAX PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICAL, JOHNSON & JOHNSON, MEDIMMUNE, INC., MERCK & CO., INC., NOVARTIS PHARMACEUTICALS CORPORATION, ORTHO BIOTECH, ORTHO MCNEIL PHARMACEUTICALS, PFIZER, INC., PHARMACIA CORPORATION, PURDUE PHARMA, L.P., RELIANT PHARMACEUTICALS, SANOFI-SYNTHELABO, INC., SCHERING-PLOUGH CORP., SMITHKLINEBEECHAM P.L.C., TAP PHARMACEUTICALS, WARRICK PHARMACEUTICALS, WYETH, AND DOES 1-100 Defendants,	CIVIL ACTION NO. 01-CV-12257 Judge Patti B. Saris

INDIVIDUAL MEMORANDUM OF BAYER CORPORATION
IN SUPPORT OF ITS MOTION TO DISMISS

In two settlements executed in January 2001 and on August 14, 2003, the state of New York settled all of its claims against Bayer Corporation ("Bayer") concerning alleged average wholesale price ("AWP") inflation and misreported best prices. The County of Suffolk has now filed an amended complaint seeking to recover for the very allegations which these settlements resolved. Plaintiff's amended complaint is rife with vague and speculative allegations, and it fails to establish standing as to Bayer or satisfy this Court's standard of particularity. For these reasons, as well as those stated in Defendants' Memorandum of Law in Support of Their Motion to Dismiss and the individual memoranda of other defendants, plaintiff's claims against Bayer should be dismissed pursuant to Federal Rules of Civil Procedure 9(b), 12(b)(1), and 12(b)(6).

BACKGROUND

In its Amended Complaint ("Complaint"), plaintiff alleges that, as a result of each defendant's unlawful scheme, it has paid more than it should have in reimbursement for defendants' drugs. (Cmplt., ¶¶ 4, 17). Specifically, plaintiff alleges that each of the defendants engaged in a fraudulent scheme to overcharge for prescription drugs paid for by Medicaid by reporting overstated AWPs for their products and promoting the resulting inflated Medicaid reimbursement to providers to increase market share. (*Id.*, ¶¶ 14, 82, 100-05). In addition, plaintiff contends that by excluding certain discounts and other inducements from the calculation of the so called "best price" paid for their products, defendants failed to report the best prices of their products as required by applicable Federal and State Medicaid laws. (*Id.*, ¶¶ 2, 8, 66, 84, 87-91). Notably, Cipro® is the only Bayer product which plaintiff specifically identifies as being "paid for by Medicaid in Suffolk County[.]" (*Id.*, ¶¶ 29, 171, 173 & Apps. A-1, B-3).

ARGUMENT

The Complaint must be dismissed as to Bayer for each of two reasons: (1) plaintiff fails to allege a cognizable claim of AWP fraud, and (2) the State of New York has settled and released any claims plaintiff might otherwise have against Bayer.

1. "[The] threshold question in every federal case" is "whether the plaintiff has made out a 'case or controversy' between himself and the defendant within the meaning of Article III." *Warth v. Seldin*, 422 U.S. 490, 498 (1975). As this Court previously recognized in the context of this multi-district litigation, plaintiff can only proceed with its AWP claims against Bayer to the extent it paid for Bayer products. *See In re Pharm. Indus. AWP Litig.*, 263 F. Supp. 2d 172, 193-94 (D. Mass 2003). Not only must plaintiff satisfy Article III, but it must do so with the particularity required by Federal Rule of Civil Procedure 9(b). *Hayduk v. Lanna*, 775 F.2d 441, 443-44 (1st Cir. 1985) (state law fraud claims alleged in Federal court must satisfy Rule 9(b)). To do so under the standard established in this Court's May 13, 2003 decision, plaintiff must "clearly and concisely" allege the specific Bayer products for which it has paid and their allegedly fraudulent AWPs. *In re Pharm. Indus. AWP Litig.*, 263 F. Supp. 2d at 194.

Cipro® is the only Bayer product which plaintiff specifically identifies as being "paid for by Medicaid in Suffolk County[.]" (Cmplt., ¶¶ 29, 171, 173 & Apps. A-1, B-3). Cipro® is a self-administered pill not covered under Medicare Part B. Although plaintiff contends that "Bayer has engaged in similar inflationary practices in prior years resulting in comparable damage to Suffolk for all covered drugs" (Cmplt., ¶ 172), its attempt to sweep unidentified Bayer drugs within the scope of this action must be rejected. As this Court previously admonished other claimants with similarly vague allegations, plaintiff must meet Rule 9(b)'s requirements by particularizing exactly what drugs were paid for and "exactly what the fraud is[.]" *In re Pharm. Indus. AWP Litig.*, Tr. of Jan 13, 2003 Hearing on Mot. to Dismiss, at 74. At a minimum, plaintiff lacks standing to assert its AWP claims as to any other Bayer drugs and such claims must be dismissed. *See In re Pharm. Indus. AWP Litig.*, 263 F. Supp. 2d at 193-94 (dismissing association plaintiffs who failed to allege specific members who purchased specific drugs).

As to the one Bayer product plaintiff actually identifies – Cipro® – plaintiff is unable to muster any cognizable claim of fraud. Plaintiff's attempt to allege a fraudulent AWP for Cipro® by referring to its own "investigation" is unavailing. (Cmplt., ¶ 171). Although purporting to

reveal an "estimated" overcharge of 27%, these allegations do not indicate the nature of plaintiff's investigation or how it calculated the "Estimated True AWP." (*Id.*) Moreover, plaintiff's AWP allegations against Bayer rely solely upon the 2001 settlement. (*Id.*, ¶¶ 175-78).

Plaintiff's attempt to give substance to its otherwise wholly speculative allegations by waving the flag of Bayer's 2001 settlement is improper and unavailing. First, the terms of the settlement agreement specifically provide that it "does not constitute an admission by Bayer or evidence of any liability or wrongful conduct." (Ex. 1, 2001 State Settlement Agreement (New York), Part II(G)).[1] Second, and even more fundamentally, the settlement makes no mention of Cipro® and thus provides no support for plaintiff's allegations that Bayer fraudulently inflated the AWP of Cipro®. To the contrary, the settlement involved four different Bayer products – Koate-HP®, Kogenate®, Konyne-80®, and Gamimune® – all of which are physician-adminstered drugs covered under Medicare Part B. (*See id.*, Part II(C)). Plaintiff cannot simply rely on the allegations of fraud resolved as to the four Part B products addressed in the 2001 settlement to impute wrongdoing regarding the one, non-Part B drug identified in its complaint. *Asarco, Inc. v. Kadish,* 490 U.S. 605, 615 (1989) (noting that the doctrine of standing is not a "gaming device" that plaintiffs may surmount merely by aggregating allegations).

Plaintiff's allegations of fraudulent AWP inflation are unrelated to the one Bayer product for which it allegedly paid. Plaintiff has, therefore, failed to satisfy this Court's standard of "clearly and concisely" alleging "exactly what the fraud is[.]" *In re Pharm. Indus. AWP Litig.*, 263 F. Supp. 2d at 194 & Tr. of Jan. 13, 2003 Hearing on Mot. to Dismiss, at 74. Consequently, plaintiff's AWP claims as to Cipro® must be dismissed. *See United States ex rel. Gublo v. NovaCare Inc.*, 62 F. Supp. 2d 347, 354-56 (D. Mass. 1999) (dismissing Medicare fraud claims because plaintiff failed to allege why or how defendant's price representations were fraudulent).

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[1] In light of plaintiffs' reference to these settlements in the Complaint, the Court may take judicial notice of their contents in considering a Rule 12(b)(6) motion. *See Watterson v. Page*, 987 F.2d 1, 3 (1st Cir. 1993); *see also Romani v. Shearson Lehman Hutton*, 929 F.2d 875, 879 n. 3 (1st Cir. 1991); *Fudge v. Penthouse Int'l*, 840 F.2d 1012, 1015 (1st Cir. 1988), *cert. denied*, 448 U.S. 821 (1988).

In any event, plaintiff's AWP claims are all barred by the 2001 settlement.[2] Plaintiff admits as much, recognizing that "[t]he 2001 Bayer settlement may resolve any claims Suffolk has with respect to the drugs at issue there[.]" (Cmplt., ¶ 180). On this point, plaintiff is correct. The 2001 settlement resolved allegations that Bayer inflated the AWPs of the drugs Koate-HP®, Kogenate®, Koyne-80®, and Gamimune® from January 1993 through August 1999. (Ex. 1, Part II(C)). Thus to the extent plaintiff attempts to sweep within its generalized, unspecific claims of AWP inflation any of the Bayer products covered by the 2001 settlement, the settlement itself (as well as principles of standing and Rule 9(b)) preclude those claims.

2. Plaintiff's best price allegations are similarly without merit. Again, plaintiff's claims rest solely on invocation of a government investigation and the resulting settlement. (Cmplt., ¶¶ 11, 92-93, 173, 179). But the 2003 settlement on which plaintiff relies bars the very claims at issue. (Ex. 2, 2003 Settlement Agreement and Release (New York), Sec. II(H)). That settlement releases Bayer from "any civil or administrative claims for damages or penalties that the state of New York has or may have relating to the Covered Conduct." (*Id.*, Sec. III(2)). The Covered Conduct addresses exactly that for which plaintiff now seeks relief – namely, failing to disclose the best prices for Cipro® and Adalat®, resulting in underpayment of Medicaid rebates for those drugs. (*Id.*, Sec. II(F)).

Plaintiff tries to minimize the preclusive effect of the 2003 settlement, claiming that it "purports to resolve only one or two years of . . . overcharges." (Cmplt., ¶ 180). That is incorrect. The 2003 settlement explicitly releases Bayer from the best price allegations addressed therein from the third quarter of 1995 to the third quarter of 2000. (Ex. 2, Sec.

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[2] Having settled with the Federal and State governments, Bayer submits that Plaintiff – as a subordinate body of State government – has no further recourse against Bayer. *See* 42 U.S.C. § 1396 (establishing Medicaid as a cooperative system between the Federal and State governments); 42 U.S.C. § 1396r-8 (contemplating a rebate arrangement between the Secretary of the Department of Health and Human Services and individual manufacturers); N.Y. Soc. Serv. Law § 367-b (providing that State pays medical providers directly and social service districts subsequently reimburse State for their share of expenditures).

II(F)(i)). Moreover, in addition to resolving the best price allegations regarding Cipro® and Adalat® for the stated time period, the 2003 settlement incorporates the filings in the underlying Federal criminal action. (*Id.*, Sec. II(F), p. 4). Thus the 2003 settlement releases Bayer from liability for *any* conduct which was the subject of the Federal investigation *or known to the U.S. Attorney at the time of settlement.* (Ex. 2, Plea Agreement, Sec. 4). To the extent plaintiff attempts to extend its allegations of best price malfeasance as to any of the drugs at issue in the 2001 settlement, its claims are also barred by that settlement. The 2001 settlement, in addition to addressing AWP, settled allegations that Bayer misreported the best price (and thereby underpaid Medicaid rebates) for Koate-HP®, Kogenate®, Konyne-80, and Gamimune. (Ex. 1, Part II(C)(iv)). Taken together, the 2001 and 2003 settlements dispose of any and all best price claims plaintiff purports to assert against Bayer with respect not only to Cipro®, but also the four Medicare-covered products.[3]

In sum, plaintiff alleges that it purchased one Bayer product – Cipro®. Plaintiff's claims of AWP fraud as to Cipro® fail because they refer solely to a 2001 Bayer settlement pertaining to Medicare-covered products that had nothing to do with Cipro®. Plaintiff's claims of best price fraud as to Cipro® fail because they are barred by the 2003 settlement. To the extent plaintiff seeks to sweep other Bayer products into its Complaint, those claims are barred by principles of standing and pleading requirements under Rule 9(b) as well as (with respect to Koate-HP®, Kogenate®, Konyne-80, and Gamimune) the 2001 settlement.

[3] If plaintiff's allegations are intended to cover a broader time period than the 2001 and 2003 settlements or to allege inflated AWPs or best pricing malfeasance as to any drugs not mentioned therein, plaintiff has clearly failed to meet even the minimal pleading requirements of Rule 8, let alone the heightened standard of Rule 9(b). *M&I Heat Transfer Products, Ltd. v. Wilke*, 131 F. Supp. 2d 256, 261 (D. Mass. 2001) (requiring a plaintiff asserting a fraud claim to specify the who, what, when, where, and why of the fraud).

CONCLUSION

For the foregoing reasons, as well as those stated in Defendants' Memorandum of Law in Support of Their Motion to Dismiss and the individual memoranda of other defendants, Bayer requests that the claims against it in the Amended Complaint be dismissed.

Dated: September 15, 2003

Respectfully submitted,

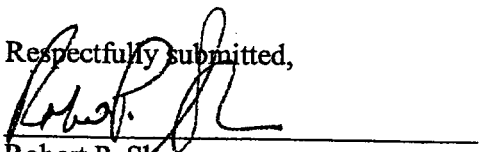

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Exhibit 1

State Settlement Agreement

Part I: Parties

This Settlement Agreement (hereinafter the "Agreement") is entered into by and between the STATE OF NEW YORK (hereinafter the "STATE") and BAYER Corporation (hereinafter "BAYER") (hereinafter collectively referred to as the "Parties") through their authorized representatives.

Part II: Preamble

As a preamble to this Agreement, the Parties agree to the following:

A. BAYER Corporation is a corporation organized under the laws of Indiana. Its headquarters are in Pittsburgh, Pennsylvania. BAYER is a manufacturer of pharmaceutical and biological products. Miles, Inc. and Cutter Laboratories, Inc. (which along with BAYER Corporation, shall be referred to hereafter as "BAYER"), were predecessor organizations that ultimately were merged into the company that became known as BAYER Corporation. At all relevant times, BAYER manufactured, marketed and sold certain drugs and biological products to – among others – (1) healthcare providers, (2) "full-line" drug wholesalers, and (3) specialized drug wholesalers sometimes called "distributors."

B. The STATE contends that BAYER caused to be submitted claims for payment to the STATE's Medicaid Program, established by Title XIX of the Social Security Act.

C. The STATE contends that it has civil claims against BAYER under various state statutes and common law for engaging in the following conduct during the period January 1993 through August 1999 involving the marketing and sale of Koate-HP

Antihemophilic Factor (Human), Kogenate Antihemophilic Factor (Recombinant), Konyne-80 Factor IX Complex (Human), Gamimune N, 5% Immune Globulin Intravenous (Human, 5%), Gamimune N, 10% Immune Globulin Intravenous (Human, 10%), and Thrombate III Antithrombin III (Human) (collectively referred to hereafter as the Qui Tam Drugs):

i) The STATE contends that BAYER, in a manner similar to the practices of certain other manufacturers, knowingly and intentionally engaged in a marketing scheme whereby it set the Average Wholesale Prices ("AWPs") of the Qui Tam Drugs at levels far higher than what the vast majority of its customers actually paid for these products when purchasing either directly from BAYER or through a wholesaler. Because the majority of Medicaid programs use AWP as a benchmark in determining reimbursement rates, the STATE contends that as a result of BAYER's actions, BAYER's customers received reimbursement from state Medicaid programs at levels far higher than their actual costs.

ii) The STATE also contends that BAYER knowingly and intentionally misled certain state Medicaid programs that reimburse on the basis of Wholesale Acquisition Cost ("WAC") by, among other actions, representing to third party reporting services such as First DataBank and Medi-Span that it did not sell the Qui Tam Drugs through wholesalers and by misleading Medicaid officials about the prices it charged to wholesale purchasers in order to avoid reporting accurate

wholesale or distributor price information that would have affected the reimbursement levels of the Qui Tam Drugs in states that use WAC as the reimbursement benchmark. As a result, the STATE contends that BAYER's customers received reimbursement from the state Medicaid programs at levels far higher than their actual costs.

iii) The STATE also contends that BAYER knowingly and intentionally misled certain state Medicaid programs that rely on actual acquisition cost information about the prices at which BAYER sold the Qui Tam Drugs to its customers, including home health agencies. The STATE alleges that BAYER did so by falsely reporting its prices on surveys and by providing invoices to home health companies that did not reflect the actual net cost of the Qui Tam Drugs to customers. As a result, the STATE contends that BAYER's customers received reimbursement from the state Medicaid programs at levels far higher than their actual costs.

iv) The STATE contends that BAYER knowingly and intentionally misreported and underpaid its Medicaid Rebates for the Qui Tam drugs, *i.e.*, the amounts that it owed to the Medicaid program under the federal Medicaid Rebate Program, 42 U.S.C. § 1396r-8. BAYER generally was required on a quarterly basis to rebate to each state Medicaid program the difference between the Average Manufacturer Price and "Best Price," as defined by 42 U.S.C. §§ 1396r-8(k)(1) and 1396r-8(c)(1)(C). The STATE alleges that BAYER misreported and

underpaid its Medicaid rebates to all states by calculating its Best Prices for the Qui Tam Drugs without factoring in the value of discounts, rebates, short-dated goods discounts, unrestricted educational grants, free goods, chargebacks, and other price reductions which were not disclosed to the states or the federal government or the Medicaid programs.

BAYER's conduct and transactions referenced herein Paragraph II(C)(i-iv) are hereinafter referred to as the "Covered Conduct."

D. The STATE contends that it has certain administrative claims against BAYER for administrative and monetary penalties under state and federal law for the Covered Conduct.

E. BAYER denies the STATE's contentions as set forth in Paragraphs II (B – D) and denies that it has any liability relating to these allegations.

F. In order to avoid the delay, uncertainty, inconvenience and expense of protracted litigation of these claims, and as a result of mutual desire to settle their disputes, the Parties reach a full and final settlement as set forth below.

G. This Agreement does not constitute an admission by BAYER or evidence of any liability or wrongful conduct.

H. Concurrent with this Agreement, BAYER is entering into a settlement agreement regarding the Covered Conduct with the United States of America and with the relator (the "Relator") in a lawsuit filed pursuant to the qui tam provisions of the federal False Claims Act, Civil Action No. 95-95-1354 (S.D. Fla., under seal), and BAYER also is entering into a Corporate Integrity Agreement with the Office of

Inspector General of the United States Department of Health and Human Services and into similar settlement agreements with numerous other states.

Part III: Terms and Conditions

NOW, THEREFORE, in consideration of the mutual promises, covenants, and obligations set forth below, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. (a) BAYER agrees to pay the United States, the individual states and the Relator the maximum collective sum of fourteen million dollars ($14,000,000) (the "Settlement Amount"). BAYER agrees to make payment of the federal share of the Settlement Amount and the Relator's share of the Settlement Amount pursuant to the terms of BAYER's separate settlement agreement with the United States and the Relator. BAYER agrees to pay the maximum sum of six million, one hundred seventy-two thousand dollars ($6,172,000) of this total (the "Total State Settlement Amount"), representing the state-funded portions of the claims settled for the participating states' Medicaid programs, to the participating states identified on Exhibit "A" to this Agreement. The STATE's share of the Total State Settlement Amount is $1,319,989.28 (the "Individual State Settlement Amount").

   (b) Within three business days of the Effective Date of the federal settlement agreement, the Effective Date of the Corporate Integrity Agreement or the execution of an escrow agreement with the State of New York, whichever is later, BAYER shall deposit the Total State Settlement Amount in an interest bearing escrow account under the custody and control of the State of New

York Medicaid Fraud Control Unit, which shall act as Escrow Agent and shall retain such funds until their release in accordance with the payment terms set forth in c).

(c) The STATE shall be entitled to disbursement of its Individual State Settlement Amount from the escrow account ten days after receipt by the Escrow Agent of a copy of this Agreement executed by both the STATE and BAYER; provided, however, that the STATE shall not be entitled to disbursement of the Individual State Settlement Amount until the Escrow Agent has received fully executed state settlement agreements from all those states identified on Exhibit "B" (the "Threshold States") . Any escrowed funds not disbursed within 200 days after the Escrow Agent has received the Total State Settlement Amount shall be disbursed to BAYER.

2) Subject to the exceptions in Paragraph III(6) below, in consideration of the obligations of BAYER set forth in this Agreement, conditioned upon BAYER's payment in full of the Individual State Settlement Amount, the STATE (on behalf of itself, its officers, agents, agencies and departments) agrees to release BAYER, its parent corporation(s), subsidiaries and affiliates, predecessors, successors and assigns as well as its current and former directors, officers, employees, agents and shareholders from any civil or administrative monetary claim, action, suit or proceeding the STATE has or may have under any source of law for the Covered Conduct. The payment of this settlement amount fully discharges BAYER from any obligation to pay restitution, damages, and or any fine or penalty to the STATE for the Covered Conduct.

3) In consideration of the obligations of BAYER set forth in this Agreement, conditioned upon BAYER's payment in full of the Individual State Settlement Amount, the STATE agrees to release and refrain from instituting, directing or maintaining any administrative claim or any action seeking exclusion from the Medicaid program against BAYER, its parent corporation(s), subsidiaries and affiliates, predecessors, successors and assigns as well as its current and former directors, officers, employees, agents and shareholders for the Covered Conduct as relates to the STATE's Medicaid program, except as reserved in Paragraph III(6), below, and as reserved in this Paragraph.

4) In the event that any person(s) has(have) filed any qui tam "whistleblower" actions under the laws of the STATE relating to the Covered Conduct, it is the STATE's understanding that: such person(s) shall take such actions as are necessary and appropriate to dismiss said actions against BAYER and secure state court approvals, to the extent necessary, of this Agreement; and, the STATE agrees that it shall negotiate in good faith with the person(s) as to the person's(s') share in connection with the state action. In the event that an agreement cannot be reached, the STATE agrees that it shall submit that issue to the state court having jurisdiction. The STATE shall also join in any necessary motions before the state court to secure approvals of this Agreement.

5) BAYER fully and finally releases the STATE, its agencies, employees, servants, and agents from any claims (including attorneys fees, costs, and expenses of every kind and however denominated) which BAYER has asserted, could have asserted, or may assert in the future against the STATE, its agencies, employees, servants, and agents,

related to the Covered Conduct and the STATE's investigation and prosecution thereof.

6) Notwithstanding any other terms of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including BAYER) are any and all of the following:

(a) Any civil, criminal or administrative claims arising under Title 26, U.S. Code (Internal Revenue Code) or the STATE's Revenue Code;

(b) Any criminal liability;

(c) Except as explicitly stated elsewhere in this Agreement, any administrative liability, including mandatory exclusion from any state health care programs;

(d) Any civil or administrative liability that BAYER has or may have under any state statute, regulation or rule not released in Paragraph III(2) above;

(e) Any claims based upon such obligations as are created by this Agreement;

(f) Any express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services, provided by BAYER;

(g) Any claims for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

(h) Any claims based on a failure to deliver items or services due; and,

(i) Any civil or administrative claims against individuals, including current or former directors, officers, employees, agents or shareholders of defendant BAYER, who are criminally convicted in relation to the Covered Conduct.

7) BAYER has entered into a Corporate Integrity Agreement with the Office of the Inspector General of the United States Department of Health and Human Services ("OIG"), the goal of which is to ensure the accurate and complete communication of drug pricing information to specified drug price reporting services and the states. BAYER acknowledges that the OIG may share information provided under the Corporate Integrity Agreement with the STATE and that the Corporate Integrity Agreement does not preclude the STATE from taking any appropriate action against BAYER for future conduct under the STATE's laws.

8) BAYER shall report certain drug and biological product pricing information to the STATE's Medicaid Program as set forth herein for the purpose of furnishing the STATE with true pricing information that accurately reflects the prices at which actual purchasers buy the drug and biological products sold by BAYER. BAYER understands that this information may be relied upon by the STATE in establishing reimbursement rates for drugs and biological products.

   a) Price Reporting: Thirty days after the last day of each calendar quarter, BAYER shall report, in accordance with sub-paragraph (b), the average sale price of each of its drugs and biological products identified by BAYER'S NDC codes that are or shall be reimbursed by the STATE's Medicaid Program, to First DataBank and to the STATE's Medicaid Program, except that the first such report shall be submitted on February 28, 2001, or fifteen days after the Effective Date of this Agreement, whichever is later. If appropriate to reflect changes in the sources from which the STATE's Medicaid program

receives its pricing information, BAYER agrees that, upon the receipt of a written request from the STATE, it will report the prices to a drug pricing reporting source other than, and in addition to, First DataBank, subject to reasonable provisions equivalent to those in place with First DataBank to ensure the confidentiality of that information.

b) Average Sale Price Reporting Procedure: The price reported by BAYER with respect to each dosage form, strength and volume of the drug or biological product (without regard to any special packaging, labeling, or identifiers on the dosage form or product or package), shall be the average of all final sale prices charged by BAYER for the drug or biological product in the United States to all purchasers, excluding those sales exempt from inclusion in the calculation of "Best Price" for Medicaid Rebate Program purposes, pursuant to 42 USC § 1396r-8, and direct sales to hospitals. The prices identified in the calculation of the average sale price should be net of all the following: volume discounts; prompt pay discounts; cash discounts; chargebacks; short-dated product discounts; free goods; rebates" and all other price concessions provided by BAYER to any relevant purchaser, as earlier defined in this paragraph, that result in a reduction of the ultimate cost to the purchaser. Notwithstanding the foregoing, the average sale price shall not include the value of bona fide charity care or grants. The average sale price reported shall be properly weighted to reflect

the volume of sales at each sale price, *i.e.*, for each NDC code, the price reported shall be an average per unit price determined by dividing the sum of all final prices charged by BAYER, net of all price reductions as defined above, for a drug or biological product in a quarter by the total number of units of that drug or biological product sold in that quarter. The methodology by which BAYER has calculated average sale prices in accordance with these standards shall be identified to the STATE as provided in Paragraph III.8(d).

c) Limitations on Reporting of Average Wholesale Price: With respect to the Qui Tam Drugs, BAYER shall not report an AWP to First DataBank, or any other reporting service, to be used for purposes of setting Medicaid reimbursement prices for the Qui Tam Drugs, and BAYER shall expressly inform such reporting services to this effect. This restriction shall not limit BAYER's ability to report AWP information for the Qui Tam Drugs to price reporting services for uses unrelated to Medicaid, or its ability to report AWP information for any purposes for drugs or biological products other than the Qui Tam drugs.

d) Certification Requirement: With each report of average sale price information BAYER sends to the STATE Medicaid Agency, BAYER shall also provide a detailed description of the methodology used to calculate the average sale price. A high managerial agent of BAYER

* The term "rebate" as used here is not understood to include any payments made by BAYER to the States pursuant to the Medicaid Rebate Program.

will certify that the average sale prices reported therein are the prices that have been reported to First DataBank, or any successor reporting agency, and that they have been calculated in accordance with the described methodology. Said certification shall be in the form annexed to this Agreement and shall include an acknowledgment that the average sale prices reported will be filed with and used in the administration of the STATE's Medicaid program. To the extent that BAYER's methodology involves accruing for the impact of future events, BAYER shall include a description of its accrual methodology in its certification, and shall on a quarterly basis evaluate such methodology in light of its actual experience and make any appropriate adjustments.

e) It is understood that BAYER considers the average sale price information and the methodology by which it is calculated to be confidential commercial information and proprietary trade secrets that if disclosed would cause substantial injury to the competitive position of BAYER. It is further understood, however, that all information provided by BAYER to the STATE Medicaid Program pursuant to this Agreement shall be made available to the STATE's MFCU upon request.

f) BAYER agrees to submit average sale price information in accordance with this paragraph for a period of five years from the Effective Date of this Agreement.

g) BAYER shall retain all workpapers and supporting documentation relating to the average sale prices of its drugs for six years after the date of each certification and will make such documentation available for inspection by the STATE's Medicaid Program and the STATE's MFCU.

9) BAYER waives and will not assert any defenses BAYER may have to any criminal prosecution or administrative action relating to the Covered Conduct, which defenses may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the United States Constitution or any corresponding section of the STATE's Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the United States Constitution or the corresponding section of the STATE's Constitution, this settlement bars a remedy sought in such criminal prosecution or in any administrative action that has not been released pursuant to this Agreement.

10) BAYER covenants to cooperate fully and truthfully with the STATE in any ongoing investigation or investigation commenced within five years of the Effective Date of this Agreement of individuals and entities not specifically released by this Agreement (including any parties with whom BAYER has or has had a business or professional relationship, including but not limited to vendors, contractors, partners, joint venturers, physicians, and referral sources) relating to the Covered Conduct. More specifically, upon reasonable request from the STATE:

(a) BAYER will make reasonable efforts to facilitate access to, and encourage the cooperation of, its current and former directors, officers, and

employees for interviews and testimony relating to the Covered Conduct, consistent with the rights and privileges of such individuals. To encourage the cooperation of such individuals, BAYER agrees to advise such individuals in writing that the STATE wishes to interview them or seek their testimony, and that the individuals' cooperation is in the best interest of BAYER. Cooperation provided pursuant to this subparagraph will include identification of witnesses who, to BAYER's knowledge, may have material information related to the STATE's inquiry. The testimony referred to in this paragraph includes, but is not limited to, testimony deemed necessary by the STATE or a court to identify or establish the source, original location, authenticity, or other evidentiary foundation for any documents and to authenticate such documents in any criminal, civil and administrative investigations and proceedings in which the STATE is involved.

(b) BAYER will provide copies of non-privileged documents and records in its possession, custody or control relating to the Covered Conduct and relating to the subject of the STATE's inquiry. In connection with this, BAYER shall provide such technical assistance as is necessary to facilitate the STATE's access to any computerized information covered by this Paragraph.

(c) Nothing in this agreement shall be construed as a waiver by BAYER of its attorney-client privilege or work product privilege. Notwithstanding that